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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/319,541	08/19/1999	RAINER H. MULLER	62-659-50781	3247

20736 7590 02/26/2002

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EXAMINER	
SHARAREH, SHAHNAM J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 02/26/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/319,541	MULLER, RAINER H.	
	Examiner	Art Unit	
	Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-9,13,15,16 and 19-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-9,13,15,16 and 19-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 4, 2002 has been entered.

Status of the Claims

2. Claims 1-2, 4-9, 13, 15-16, 19, 20-30 are now pending. Claims 1, 2, 13, 19-27, 29 are independent claims.

Any rejection that is not addressed in this Office Action is considered obviated in view of persuasive arguments.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-9, 21-22, 25 and all dependent claims thereof are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 2, 21, and 22, the phrase "in case of cellulose the portion of the matrix material phase of formulation is 70%-98% " renders the claim ambiguous. It is not clear what is the relationship between cellulose and the recited weight percentages 70-98%.

Is 70-98% the weight of cellulose, or is it the weight of matrix material, or is cellulose used as the polymeric matrix material in amounts of 70-98%? Applicant is requested to clarify the claim language.

Claim Objections

4. Claims 4-8 are objected to because of the following informalities: claims 4-8 are improperly dependent on claims 19-22 which improperly follows claims 4-8. Accordingly, the sequence of dependency is not proper. Appropriate correction is required.

A series of singular dependent claims is permissible in which a dependent claim refers to a preceding claim which, in turn, refers to another preceding claim.

A claim which depends from a dependent claim, should not be separated by any claim, which does not also depend from said dependent claim. It should be kept in mind that a dependent claim may refer to any preceding independent claim. In general, applicant's sequence will not be changed. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application

being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 1, 4-6, 8, 13, 15-16, 19, 20, 23-24, 26-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al US Patent 5,202,159.

The instant independent claims are directed to formulations comprising an matrix material phase, an excipient phase, and an active substance phase.

Chen discloses methods of preparing sodium diclofenac enteric coated comprising dissolving sodium diclofenac (active substance) in water to form a solution, then add an amount of excipiet to the solution to form a suspension, then add Eudragit L 30D (a polymeric moiety) to the mixture, and finally atomize the slurry to form spray-dried powder (see abstract, col. 8-lines 26-55). Chen formulates his powder by using the same components as instantly claimed, in the same concentrations via the same process steps; namely spray drying (see col 4, table I, item V). Accordingly, Chen's powder inherently possesses the same coherency characteristics as instantly claimed formulations, because Chen uses the same precursor compounds and method steps to formulate his powder as instantly claimed formulations. Thus, Chen anticipates the limitations of the instant claims.

7. Claims 19, 21, 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Bauer et al US Patent 4,693,750.

The instant claims are directed to formulations comprising a matrix matrial phase and an excipient prepared by spray drying method.

Bauer discloses tabletting agents comprising a polymeric moiety such as cellulose and an excipient such as lactose dissolved in water and then spray dried (see col 2, lines 55-67; col 4, lines 17-45). Bauer uses the same components and method steps as the instant claims; thus, Bauer's tabletting agent possesses the same functional characteristics as the instant formulations. Accordingly, Bauer anticipates the limitations of the instant claims.

8. Claims 1-2, 4, 8, 13, 15-16, 19, 20, 22-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Norling et al US Patent 5,958,458.

The instant independent claims are directed to formulations comprising an matrix material phase, with an excipient phase (claims 1-2, 21, 23) or without an excipient phase (claims 20, 22, 24), which can further contain an active substance phase (claims 1-2, 20, 22, 24, 26-27, 29) or be without an active substance phase (claims 21, 23). Norling meets the limitations of these claims.

In example 1, Norling discloses preparing a suspension containing an excipient such as calcium carbonate and a polymeric binder such as PVP and then spray drying the suspension to form calcium carbonate spherical pellets (see col 21, lines 10-45). In addition, Norling specifically discloses that cellulose or its derivatives can be used as the binder similar to PVP (see col 13, lines 51-60). Norling uses the same components and methodology as the instant claims; subsequently, his pellets possess the same coherency characteristics as instantly claimed. Thus, Norling anticipates the limitations of claims 23.

Furthermore, Norling discloses preparing a suspension comprising theophylline (an active drug) with calcium carbonate (an excipient) and PVP (a polymer) in water, and then spray drying the mixture to produce particles or pellets having friability of 2.5% after 5 minutes testing (examples 2-3; see also *col 17, lines 55-60*). Norling specifically discloses that his pellets are free flowing (*col 22, lines 8-11; col. 26, line 60-67).* Further, Norling discloses forming theophylline tablets by directly compressing his pellets (*example 12*). Accordingly, Norling uses the same components and methodology as the instant claims; thus, his pellets possess the same coherency characteristics as instantly claimed, meeting the limitations of the instantly claimed formulations.

9. Applicant's arguments filed on December 4, 2002 have been fully considered but are not found persuasive. Applicant argues that Norling does not describe a compound particle for direct compression as the present claims. Applicant also asserts that just because Norling teaches controlled release pellets, does not mean that the structure of Norling's pellets is identical to the claimed invention. Applicant further adds that unlike the instantly claimed invention, Norling uses spray-drying to produce cores of his pellets which is then coated.

In response to applicant's argument that Norling's particles are not for directed compression and that Norling uses spray-drying to produce the core of his pellets, "a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of

making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In the instant case, regardless of the intended use of Norling's pellets, Norlings's post spray-drying particles of pellets meets the limitations of the instant formulations and method claims, because they meet all the elements of the instantly claimed formulations, as well as, method steps.

Applicant's argument that Norling's core is coated and then compressed is noted, yet, it is not persuasive. First, Examiner states that during the prosecution the limitations of the claims are viewed given their broadest reasonable interpretation. Accordingly, Norling's reference is anticipatory because none of the instantly pending claims exclude the argued features of Norling's pellets or their respective tablets. Thus, applicant's arguments with respect to such features of Norling's teachings are not commensurate with the scope of the pending claims.

Second, the instant claims are limited to formulations resulting after the dispersion of the process claims are subjected to spray-drying step. Not, their ability to provide controlled-release properties after they are compressed. Such functional limitations and abilities are inherent to the pellets of Norling, because Norling uses the same components and same methodologies to prepare his core pellets. Accordingly, Norling's core anticipates the limitations of the instant claims directed to a formulation.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 5-9, 21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Norling et al US Patent 5,958,458 in view of Bauer et al US Patent 4,693,750.

The teachings of Norling et al and Bauer et al are discussed above. Both Norling and Bauer teach preparing tablet formulations by directly compressing spray dried powder, thus, their teachings are analogous.

Norling et al fail to use cellulose or its derivatives in concentrations of 78-90%, but they do suggest the use of cellulose as a suitable binder in their compositions (col 13, lines 50-60).

Bauer et al teaches lactose and cellulose as suitable tabletting agents in preparing pharmaceutically active formulations (see abstract). However, Bauer fails to use an active agent in his slurry formulation prior to his spray drying step.

Although, Norling et al do not use cellulose or its derivatives in the core component of their composition, it would have been obvious to one of ordinary skill in the art at the time of invention to use higher concentrations of cellulose, as suggested

by Bauer, in the Norling's suspension prior to his spray drying step, and then optimize the amount of cellulose in that suspension by routine experimentation to provide oral dosage formulations with desirable release properties. The ordinary skill in the art would have been motivated to use cellulose in the suspension of Norling, because as taught by Bauer, he would have had a reasonable expectation of success in improving the flowablility of the tabletting agents of Norling and thus enhancing the characteristics of final oral dosage formulation.

New Matter

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 27-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are directed to time-release units, which are not supported by the originally filed applications. Time-release dosage forms are known formulations that at least provide a twofold reduction in dosing frequency as compared to the drug presented in conventional form (see Remington: The Science and Practice of Pharmacy, Vol. I, 1995 P. 598). The specification at no place teaches formulations having such property neither does it recite oral dosage forms having any time-release

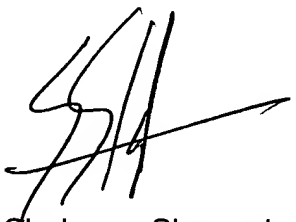
properties. Accordingly, Applicant has failed to reasonably convey possession of such product to one of ordinary skilled in the art at the time the Application was originally filed.

Conclusion

14. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on 703-308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.



Shahnam Sharareh, PharmD
Patent Examiner, Art Unit 1617

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February 24, 2002